

REMARKS

Claims 34 to 38 remain in the application and stand rejected. Applicants note appreciably that the rejections partially based on references Markel et al and Martin have been withdrawn.

Claims 34 and 35 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al (U.S. Patent No. 4,405,313). Claims 36 and 37 stand rejected under 35 USC 103(a) as being unpatentable over Sisley et al in view of Ash et al (U.S. Patent No. 5,947,953). Claim 38 stands rejected under 35 USC 103(a) as being unpatentable over Sisley et al and Ash et al in view of Cazal (U.S. Patent No. 5,800,414).

Claims 34 to 38 also stand rejected under “nonstatutory obviousness-type double patenting” in view of Serial No. 10/974,267.

Claim 34 is being amended to include the limitation that the hub member is initially separate and is releasably securable thereto by the practitioner, although this is implicitly clear as claim 34 already includes the limitation “after catheter implantation and subcutaneous tunneling” which are procedures performed by the practitioner. These amendments are both implicitly contained in the unamended claim 1 but are believed to assist the clarity of the claim. Furthermore, since the unamended claim 34 already provides the basis for the amended limitations, no new issues are raised.

The hub manages the extracorporeal catheter portions by securing together the proximal lumen portions, and also protects the tunnel exit site against any further undesirable splitting apart of the proximal lumen portions. Further, the hub member is releasable from the catheter should it become necessary to repair the catheter: the present invention also provides for repair of catheters that have already been implanted into a patient, without removing a damaged catheter from the patient and re-implanting a new one, causing accompanying distress and risk to the patient. Thus, the presently claimed invention is a greatly advantageous breakthrough in catheter implantation and repair procedures.

References Ash et al and Cazal have been discussed and distinguished in previous responses.

Reference Sisley et al sets forth an implantable dual lumen catheter assembly having a splitter (or hub) 22 affixed to both catheter lumens in the proximal end region of the assembly. Essentially, the catheter comprises two discrete, side-by-side tubes tangentially adjoined, and in the assembly the proximal end region the tubes are separated from each other and are

independently movable, proximally of the splitter 22. The intermediate assembly region becomes joined into a mechanically integral component by filler material 18a, 18b, as seen in Figure 3, which minimizes passage of bacteria along the tubes and also allows more substantial contact between the patient's tissues and the catheter to provide natural sealing. The filler material may be the same material, such as silicone, as the two tubes, or optionally could be different material that is compatible with the material of the two tubes.

It is clear in the disclosure of reference Sisley et al, implicitly, that the filler material is not added about the tubes by the practitioner but instead is fabricated to the assembly during manufacturing. Also, it is equally clear, implicitly, that the splitter 22 is also affixed to the assembly at the factory, although only the briefest of description is provided in column 5, lines 31 to 36, that it "wraps the junction of the tubes ... which separates the tubes ... and which eliminates further splitting" thereof. It cannot properly be held to be *prima facie* "obvious" to the skilled artisan, to have the practitioner perform manufacturing acts at the patient's bedside.

Regarding claim 34, Ash et al discloses in Figures 1 to 3 and 5 to 7 a hub member 24 already affixed to the catheters. The reference mentions hub 24 only at column 5, line 60 and discusses the hub only at column 11, line 60 to column 12, line 37. In order for a hub to be "adapted to be releasably attached" to a catheter by the practitioner, it must first be a separately existing component, and such a separately existing hub component is not disclosed by the reference. Furthermore, the only portion of reference Ash et al discussing the Y junction and hub 24 is column 12, lines 15 to 32, wherein it is clearly expressed that the catheter lumens terminate in the hub and the extension tubes begin within the hub; thus, the catheter lumens expressly do not extend completely through the hub beyond the proximal end of the hub. Since the hub is a part of the catheter assembly located at the proximal ends of the catheters, the site of the hub along the catheters is not selectable by the practitioner. In fact, the artisan clearly understands that, conventionally, hubs become part of catheter assemblies at the factory by being insert molded to the catheter proximal ends and extension tube distal ends at the factory to assure sealing as well as assured fluid communication between the extension tubes and the catheter lumens. Consequently, the embodiment of Ash et al having a hub (Figures 1, 1a, 2 and 5 to 7) is not of a catheter assembly capable of retrograde tunneling.

While reference Ash et al also expresses that a catheter assembly need not have any hub at all (column 12, lines 3 to 14), the reference does not express that a hub component may be added by the practitioner at a site selected by the practitioner.

No reference, nor any combination thereof, meets the claim limitation that the hub member is releasably attachable by the practitioner to portions of the catheter lumens distally of the proximal ends thereof, and Applicants respectfully traverse the rejection.

Claims 35 to 38 depend from claim 34, which is believed to patentably distinguish over the reference, and therefore, claims 35 to 38 are believed patentable.

Claims 34 to 38 stand rejected for “nonstatutory obviousness-type double patenting” in view of the claims of pending but later-filed continuation-in-part application Serial No. 10/974,267. The present rejection is only provisional, since the present application has a filing date earlier than the other application and once all other rejections of the present claims is overcome, the double patenting is required to be withdrawn and the present application issue. Applicants traverse the assertion in the Office Action that the claims of the other application which do not include a hub limitation, cover the present claims of a hub adapted to be releasably attachable to portions of catheter lumens distal of their proximal ends.

The claims are believed to distinguish patentably over the prior art, and allowance thereof is respectfully urged. No new limitations have been entered into the claims, and no new issues are raised. No new matter has been entered hereby. If any additional fees are due, please charge same to Deposit Account No. 50-2434.

Respectfully Submitted,

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February 19, 2010

Date

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